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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/424,951	SRIKANTHA ET AL
	Examiner Katharine F. Davis	Art Unit 1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 20 January 2000.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-8 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

15) Notice of References Cited (PTO-892)

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5

18) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_

19) Notice of Informal Patent Application (PTO-152)

20) Other: \_\_\_\_\_

### **DETAILED ACTION**

This Office Action is in response to the application filed on January 20, 2000. Claims 1-8 are pending in the instant application.

#### *Specification*

The disclosure is objected to because of the following informality: In the Brief Description of the Drawings each panel or drawing containing multiple panels must be referred to as a separate figure. The first line of each description must refer to each separate figure (e.g., Figures 2A-2C). Correction is required for Figures 1 and 2.

#### *Claim Objections*

Claim 1 is objected to because of the following informality: Claim 1 recites in line 3 the phrase “to polynucleotide sequence”. This objection may be overcome by amending the claim to read “to **the** polynucleotide sequence”.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 4-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the word "having" in line 1. The word "having" is not legally defined as open or closed language thus rendering the claim indefinite. Amending the claim to read "comprising" or "consisting of" would overcome this rejection.

Claim 4 is incomplete. There is no positive process step(s) which refers back to the method recited in the preamble therefore rendering the claim indefinite.

Claim 6 recites the phrase "said DNA" in line 2. There is insufficient antecedent basis for this limitation in the claim.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 5,939,306 (Alex *et al.*). Alex *et al.* disclose a histidine kinase from *Candida albicans* (cos-1) that

is involved in a two-component signal transduction system that functions in response to environmental stimuli (see figure 6-SEQ ID NO:33; column 6, Summary of the Invention and columns 7 and 8, histidine kinase function and activity). The cos-1 sequence disclosed by Alex *et al.* is nearly identical to that of the caNik1 sequence of the instant invention with only 4 mismatches over 3500 bases. This is well within the rate of sequencing error. Therefore, absent evidence to the contrary, the cos-1 gene appears to be the same gene as the gene claimed (caNik1) in the instant invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,939,306 (Alex *et al.*) in view of Timberlake (PAP Conference Discovery Mode Action

Antifungal Agent, 1995, pages 17-29; IDS Reference No. A7). Alex *et al.* is applied as above.

Additionally, Alex *et al.* teaches that the osmosensing histidine kinases can be used as targets in assays which screen compounds for activity against fungal organisms (see columns 6 and 11).

Timberlake discusses an assay system (HTS, High-throughput screening) wherein a large number of compounds can be tested for effect on growth of model organisms (see page 17).

Timberlake teaches the use of reporter genes ( $\beta$ -galactosidase and  $\beta$ -glucuronidase) that can be utilized to monitor the activity of target genes after contact with potential antifungal compounds (see entire article). Upon recognition of a kinase which can be a potential target for antifungal compounds one of skill in the art would understand that in order to assess the effect of sample antifungal compounds on the said kinase one would monitor transcription of the kinase DNA, translation of the kinase DNA and/or functional activity of the mature kinase. The histidine kinases are involved in the synthesis of the fungal cell wall and an intact fungal cell wall is required for growth of the fungal organism. Growth of the organism is required for pathogenicity. Mammalian cells do not have a cell wall. Antifungal agents which target components not found in mammalian cells decrease the potential toxicity to the host being treated with the antifungal agent. For these reasons, one of skill in the art would be motivated to use the histidine kinases as targets in screening methods for antifungal drug development.

Therefore, it would have been obvious to one of ordinary skill in the art at the time that the instant invention was made to use the fungal histidine kinases as targets in screening methods for compounds with antifungal activity.

*Conclusion*

Claims 1-8 are rejected. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katharine F. Davis whose telephone number is (703) 605-1195. The examiner can normally be reached on Monday-Friday (8:30am-5:00pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Schwartzman can be reached on (703) 308-7307. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications. Any inquiry concerning the formalities of this application should be directed to Patent Analyst Dianiece Jacobs whose telephone number is (703) 305-3388. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Katharine F. Davis  
April 23, 2001

ROBERT A. SCHWARTZMAN  
PRIMARY EXAMINER